UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,944	08/31/2001	Kevin P. Baker	P2548P1C18	2573

28457 7590 09/09/2003

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,944	BAKER ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 31August 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 22-41 are pending in the instant application. Claims 1-21 have been canceled as requested by Applicant in Preliminary Amendment B, Paper Number 3, filed August 31, 2001.

All claims are currently under examination.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Specifically, the Address of inventor Dan L. Eaton was changed, and the change was neither initialed nor dated.

Information Disclosure Statement

3. The IDS has been considered by the examiner, however, the information will not be published.

3.2 Applicants are advised that the IDS had Ashkenazi et al., and not Baker et al., as inventors.

Specification

4.1 The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, embedded hyperlinks are found on page 25, line 10, page 27, line 31, page 94, line 32 and page 96, line 13.

Appropriate correction is required.

4.2 The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Nucleic Acids Encoding PRO344 protein.

4.3 The abstract of the disclosure is objected to because it does not specifically recite the claimed invention. Correction is required. See MPEP § 608.01(b).

Formal Matters

5. The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention (see MPEP Chapter 2400 and 37 C.F.R."1.801-1.809). Examiner acknowledges the deposit of organisms under accession number ATCC 209492 under terms of the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in compliance with this requirement (see specification, pages 147-148).

Double Patenting

6. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

A sequence search of the pending and published application databases has revealed that there are a series of applications in which SEQ ID NO: 41 is present but that do not claim the

nucleic acid. However, there are numerous other applications filed by the applicants which contain the nucleic acid sequence of SEQ ID NO: 361 which is identical to the nucleic acid molecule of SEQ ID NO: 41, and which may contain possible conflicting claims. Due to the large number of applications that contain this sequence, the examiner is unable to determine if any of these applications have claims directed to this nucleic acid sequence. Applicant is required to point out to the Examiner all double patenting issues. See MPEP § 1.105.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 22-31 and 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard et al., US Patent No. 6,197,930, issue date March 6, 2001, effective priority date

August 26, 1997. The effective priority date of the instant application is December 16, 1997 (60/069,694).

Claims 22-31 and 33-41 encompass isolated nucleic acids having at least 80% nucleic acid sequence identity to a nucleic acid sequence of SEQ ID NO: 41 or full-length coding sequence of the cDNA deposited under ATCC accession number 209492 or encoding the polypeptide of SEQ ID NO: 42 or recited domains thereof, vector comprising the claimed nucleic acid, wherein the claimed nucleic acid is operably linked to control sequences, host cell comprising the vector, wherein the host cell is a CHO cell, an *E. coli* or a yeast cell, or isolated nucleic acid that hybridizes to the nucleic acid of SEQ ID NO: 41 or full-length coding sequence of the cDNA deposited under ATCC accession number 209492 or encoding the polypeptide of SEQ ID NO: 42 or recited domains thereof, wherein hybridization occurs under stringent conditions and wherein the nucleic acid is at least 10 nucleotides in length.

Sheppard et al. disclose an isolated nucleic acid molecule (SEQ ID NO: 1) that is identical to nucleotides 44-1347 of SEQ ID NO: 41 of the instant application, and that encodes a protein (zsig39, SEQ ID NO: 2) that is identical to the polypeptide of SEQ ID NO: 42 of the instant application (see attached sequence alignments). The open reading frame of SEQ ID NO: 41 is nucleotides 227-955, so the nucleic acid molecule of Sheppard et al. is identical to the coding region as well as portions of the 5' and 3' non-coding regions. The nucleic acid molecule of Sheppard et al. would hybridize to the nucleic acid of SEQ ID NO: 41 of the instant application. Sheppard et al. also teach an expression vector comprising control sequences operably linked (column 4, lines 50-64), and host cell that may be *E. coli* or a yeast cells (column

30, line 47 to column 31, line 12 and column 31, lines 46-67). Therefore, Sheppard et al. anticipates the claims.

Claim 32 is not included in the rejection because it encompasses the isolated nucleic acid comprising the nucleic acid sequence of SEQ ID NO: 41, and the nucleic acid of SEQ ID NO: 41 has a different nucleic acid sequence at the 5' and 3' ends compared to nucleic acid of Sheppard et al., and therefore SEQ ID NO: 41 is neither anticipated nor obvious.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 22-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-41 are indefinite because claims 22-27, 30, 31 and 35 encompass nucleic acid molecules encoding the extracellular domain of the protein of SEQ ID NO: 42. The specification describes a polypeptide sequence consisting of SEQ ID NO: 42, which is highly homologous to C1q complement protein, which binds to antibodies attached to the surface of a pathogen and initiates the complement activation cascade, and therefore the protein of SEQ ID NO: 42 of the instant invention is also likely to be a member of the complement family and to have this activity. Therefore, the protein identified as PRO344 is a soluble protein, and is not disclosed as being expressed on a cell surface. Accordingly, the limitation that the claimed protein comprises

an "extracellular domain" (for example see claim 22 parts (c) and (d)) is indefinite, as the art does not recognize soluble proteins as having such domains. Further, if the protein had an extracellular domain, the recitation of "the extracellular domain"..." lacking its associated signal sequence" (claim 22, part (d), for example) is indefinite as a signal sequence is not generally considered to be part of an extracellular domain, as signal sequences are cleaved from said domains in the process of secretion from the cell. The other claims are rejected for depending from claims 22, 27 and 35.

Claims 36-37 are also indefinite because they encompass an isolated nucleic acid that hybridizes under "**stringent conditions**". Though the specification on page 30 describes various hybridization and wash conditions under "stringent conditions", they are exemplary. The term **"stringent conditions"** is considered indefinite, since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 22-26 and 35-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acids having at least 80%, 85%, 90%, 95% or 99% sequence identity with a particular disclosed sequence (SEQ ID NO: 41, cDNA deposited under ATCC accession no. 209492) or encoding a particular protein (SEQ ID NO: 42). The claims do not require that the nucleic acid or encoded polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved

until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids encoding polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 42, but not the full breadth of the claims meet the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Conclusion

10.1 No claim is allowed.

10.2 The full-length sequence of SEQ ID NO: 41 is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Eileen B. O'Hara

Patent Examiner